

**Advisory Action
Before the Filing of an Appeal Brief**

Application No. 10/557,333	Applicant(s) SING ET AL.
Examiner SARAH AL-AWADI	Art Unit 1619

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 January 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: none.
Claim(s) objected to: none.
Claim(s) rejected: 24-25, 28-30.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Shanon A. Foley/
Primary Examiner, Art Unit 1619

Continuation of 11, does NOT place the application in condition for allowance because: Claims 24-25, 28, and 29-30 are rejected under 35 U.S.C. 112 2nd paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants point out that the addition element of original claims 24 and 29 were elements of the claimed apparatus referred to as a means and thus must be a structural component to the apparatus.

In response the Examiner respectfully submits that original claims 24 and 29 recite means for adding cross-linking agents, whereas the amended claims 06/23/2009 recite addition elements. It is not clear what an addition element is and if it imparts a structural limitation for the apparatus claim. The original claims do not have addition elements, but rather have a means for adding various reagents which could be numerous interpretations, open to mixing in a beaker contained in a water bath. If the cross-linking agent is the addition element it is not clear how the apparatus imparts that structure once the cross-linking agent is added because once the cross linking agent is added there is no more addition element. The Examiner respectfully submits that should Applicant's disclose that each addition element recited forms part of the apparatus, there is no support found in the specification for such an element, see reasons in office action mailed 11/19/2009. Support is found for adding cross-linking agents and polysaccharides; however such support does not impart any structural limitations to the apparatus and there is no teaching in the disclosure whether the addition elements are part of the instant apparatus or are intended to be ingredients added to a mixture.

Claims 24-25, and 28-30 are rejected under 35 U.S.C. 112 1st paragraph as failing to comply with the written description requirement. The terms "air injector", "water supply" and "addition element" are considered new matter. Applicants argue that adding air to gelatin is well known in the art and that adding water to a mixture inherently requires a water supply. With regard to addition elements, Applicants submit paragraph 022 of the instant disclosure which states that "sugars and/or polysaccharides may be added to the gelatin" thus three elements may be used within the mixture, and thus at least three addition elements may be present in the apparatus.

In response, the Examiner respectfully submits that with regards to air injector, the instant claims filed 03/20/2009 recite a "means for adding air." There are numerous ways which add air to compositions; nowhere does the instant disclosure recite a structural element such as an air injector as included with the apparatus. With regards to "water supply" the originally filed claims recite a means for adding water but do not recite that a water supply is a necessity of the apparatus. Water can be added to composition numerous ways, but it is not described in the instant disclosure a "water supply". With regards to addition element, the instant disclosure recites sugars or polysaccharides may be added to the composition. However, Applicants are reminded that the claims are drawn to an apparatus not a composition in which water or other components are added. There is no description for an apparatus with the claimed structural components.

Claims 24-25 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pawelchak et al. U.S. Patent 4,292,972 in view of Reich U.S. Patent 6,706,690. Applicants argue that Pawelchak et al. does not disclose a heat source capable of heating a mixture and expressly freeze dries the material, and that Pawelchak et al. uses carboxymethylcellulose which is known to be soluble in water. Applicants further point out that the claimed dryer is separate from the claimed heat source and both must be present in the apparatus. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., wherein the claimed dryer is separate from the claimed heat source or the exclusion of carboxymethylcellulose from the composition), are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). With regards to Applicants arguments that Pawelchak et al. does not disclose a heat source capable of heating a mixture, the Examiner submits column 4, lines 43-46 which discloses that the compositions can be prepared at room temperature or at elevated temperatures, thus the presence of a heat source is inherent when preparing the mixture with elevated temperatures, after which becomes freeze dried. The material is then lyophilized through use of a vacuum in order to dry, see column 4, lines 65-68. With regards to heating Reich et al. was relied upon to teach alternate methods of drying hemostatic materials such as freeze-drying, heat drying or spray drying, see column 4, lines 67-column 5 line 3. Heat drying would inherently require a heating element. Secondly, as Pawelchack teach blowing air into the mixture, and it is taught that mixing the ingredients can occur at elevated temperatures it would be obvious to the skilled artisan to include a heat source for mixing or for heating the air.

Claims 24-25 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ji et al. U.S. Patent 5,894,022 in view of Szymaitis U.S. Publication No. 2003/0194380. Applicants argue that Ji et al. does not appear to disclose a mixing chamber or mixing element capable of stirring the contents of the mixing chamber. Rather Ji et al. appears to disclose that a mixture exists. The composition of Ji et al. does not disclose or require the apparatus of the pending claims. Applicants argue that Ji et al. does not appear to disclose a dryer operating at a temperature above freezing or drying the composition. Applicants further argue that Ji et al. does not disclose or suggest injecting air into the composition for foaming which was relied upon by Szymaitis. Applicants note that the injecting air as to foam a composition would appear to defeat the purpose of precipitating a matrix base by heating an emulsion, thus rendering the composition unsuitable for its intended purpose. Applicants argue that Szymaitis does not appear to teach a hemostatic composition, or a method or apparatus for forming one. Lastly, Applicants argue that neither Ji et al. nor Szymaitis appear to disclose or suggest an air injector as part of an apparatus for forming a hemostatic material.

In response, the Examiner submits that Ji et al. teaches compositions which form a gel that are heated in a water bath which is a chamber. The compositions include hemostatics, column 3 line 8. The matrix composition taught by Ji can include addition elements such as gelatin, cross-linking agents, starch (polysaccharide) albumin (clot formation accelerator) and stabilizers see column 7, lines 55-67. The composition can be prepared by heating, mixing and dissolving reagents see column 7, lines 55-67. Thus as reagents are prepared by heating, mixing and dissolving, it is inherent that the composition is being mixed by an apparatus. Regarding adding air to the composition of Ji and drying, Ji et al. teaches the forming of sponges, thus it is inherent that the consistency of the sponge contains air pockets. Further Zi et al. teach that the sponges are used to create hemostasis, see paragraph 016. Zi et al. does not expressly teach a dryer, however Szymaitis et al. discloses that the prior art teaches that sponges are formed when dried, see paragraph 048 thus it is inherent that the sponges are dried. Szymaitis also teaches sponges or gauzes, See paragraph 016. The Examiner respectfully submits that injecting air would not defeat the purpose of precipitating a matrix base by heating an emulsion, because Ji et al. expressly teaches semi-solid or sponge textures. It is well known in the art that sponges contain air pockets. As both Szymaitis and Ji teach sponges there would have

been a reasonable expectation of success for injecting air into the composition taught by Zi as Zi also teaches haemostatic agents and the use of sponges. .